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I.D.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/072,994 05/05/98 COTTAREL G MIV-032.02

<input type="checkbox"/>	HM12/0919	<input type="checkbox"/>	EXAMINER
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ART UNIT	PAPER NUMBER
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1646

18

DATE MAILED: 09/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.****Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/072,994

Applicant(s)

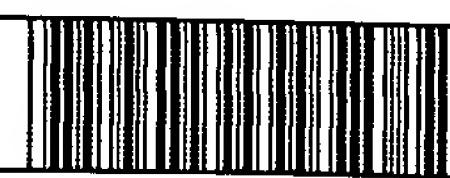
Cottarel et al.

Examiner

Michael Pak

Group Art Unit

1646

 Responsive to communication(s) filed on Jun 16, 2000 This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

 Claim(s) 1-40 is/are pending in the application. Of the above, claim(s) 1-13 and 23-36 is/are withdrawn from consideration. Claim(s) \_\_\_\_\_ is/are allowed. Claim(s) 14-22 and 37-40 is/are rejected. Claim(s) \_\_\_\_\_ is/are objected to. Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

 See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner. The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

 Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All  Some\*  None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) \_\_\_\_\_. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

 Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

 Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). 8 Interview Summary, PTO-413 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**DETAILED ACTION**

***Response to Amendment***

1. The preliminary amendments filed on 9 June 2000 (Paper No. 16) has been entered.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 14-22 and 37-40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are directed to a nucleic acid encoding a CAK1 polypeptide where CAK1 is an orphan kinase with no known substrate activity or function. The specification as filed does not disclose or provide evidence that points to a property of the claimed kinase such that another non-asserted utility would be well established. Since the function of the protein is not known because the substrate activity is not known, the protein lacks well established utility. The specification on page 2 disclose the asserted utility of using the CAK1 polypeptide in clinical

diagnosis and treatment of systemic fungemia. However, there is no nexus between the unknown properties of the CAK1 polypeptide and the diagnosis and treatment of systemic fungemia. Thus, the asserted utility lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Any utility of the nucleic acid encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The CAK1 polypeptide does not have well established utility because different kinases would have different functions directed to specific substrate and the skilled artisan would have to determine the specific function of the kinase. The closest structural identities are to many different kinases at approximately 25% sequence identity. The claimed polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its function and use. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors, host cells, and the

process of expressing the protein do not have utility because the nucleic acid without utility is needed to practice the inventions.

Claims 14-22 and 37-40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

See previous office actions for some of the enablement issues which should be considered along with the utility rejection above.

3. Claims 37-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is indefinite for recitation of ~~stringent~~ conditions~~s~~ which is a relative term and it is not clear whether the condition is high, moderate, or low stringency condition for hybridization. Claims 38-40 are dependent on claim 37.

Applicants argue that page 12 of the specification describes the stringent hybridization conditions. However, stringent conditions provided is a description of specific embodiment of

the desired result when any number of hybridization conditions are used. Furthermore, as indicated by applicant in the remarks, the results of stringent hybridization condition is in melting temperature which is a statistical analysis of binding at 50% duplex formation between DNA strands. Thus, at a given Tm there is always 50% duplex formation, thus it is not clear how one skilled in the art distinguishes what hybridizes and not hybridizes at stringent hybridization conditions.

4. No claims are allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Michael D. Pak*  
Michael Pak  
Primary Patent Examiner  
Art Unit 1646  
7 September 2000